The purpose of this e-mail is to inform you and other stakeholders about the new EGAPP Project, and to provide an opportunity for you to ask questions or provide comments or suggestions. This information is being provided to you because you were recommended by other interested individuals or because this project might have relevance to you or your organization. Questions or comments about EGAPP activities are welcome and should be directed to EGAPP@cdc.gov.

What is EGAPP?

Evaluation of Genomic Applications in Practice and Prevention (EGAPP) is a three-year model project developed by the Office of Genomics and Disease Prevention at the Centers for Disease Control and Prevention (CDC). RTI International provides technical expertise and support for the project.

The goal of the EGAPP Project is to support the first phases of a coordinated, systematic, and sustainable process for evaluating genomic applications in transition from research to clinical and public health practice. A primary focus of the project is the establishment of an independent, non-Federal Working Group composed of experts from fields such as health care, public health, human genome epidemiology, and evidence-based medicine/health technology assessment. Roles of the Working Group will include:

- prioritizing and selecting topics for review,
- establishing methods for evidence-based review and development of conclusions/ recommendations,
- overseeing expert and peer review of commissioned evidence reports, and
- developing conclusions or recommendations based on the evidence.

Why is the evaluation of genomic applications a public health issue?

The success of the Human Genome Project has led to increasingly rapid translation of genomic information into clinical practice. Genetic tests for about 1,100 diseases have been developed, with more than 800 currently available for clinical testing. Most are used for diagnosis of rare genetic diseases, but a growing number have population-based applications, including carrier identification, predictive testing for inherited risk for common diseases, and pharmacogenetic testing for variation in drug response. These tests, and other anticipated applications of genomic technologies for screening and prevention, have the potential for broad public health impact.

As consumer interest in ─and demand for ─ new genomic technologies continues to rise, it creates an increasingly urgent need for timely and reliable information that will allow health care providers and payers, consumers, and policy makers to distinguish tests that are safe and useful. Recommendations on the development of safe and effective genetic tests have been produced by expert panels, professional organizations, and clinical experts (e.g., Task Force on Genetic Testing, Secretary's Advisory Committee on Genetic Testing). However, a coordinated

approach for effectively translating genomic applications into clinical practice and health policy has not yet been developed.

This project intends to integrate existing recommendations for action with knowledge gained from previous CDC initiatives (e.g., ACCE project; http://www.cdc.gov/genomics/activities/fbr.htm), existing processes for evaluation and appraisal (e.g., United States Preventive Services Task Force), and the international health technology assessment experience in order to establish and evaluate a systematic mechanism for evaluation of genomic applications in health practice in the United States.

Project Activities

Expert Meeting

In January, 2005, the EGAPP sponsored *Expert Meeting on Evidence-Based Review of Genomic Applications* was held to consider methodological approaches for evidence-based review of genetic tests and other genomic applications. http://www.cdc.gov/genomics/gtesting/EGAPP/meetings.htm

EGAPP Working Group

In April, 2005, the twelve members of the independent EGAPP Working Group were announced (http://www.cdc.gov/genomics/gtesting/egapp.htm#wgroup).

The first meetings of the Working Group will take place in Atlanta, GA on May 18-19 and July 18-19, 2005.

If you are interested in attending a Working Group meeting, more information can be obtained by emailing EGAPP@rti.org.

Stakeholders

A key project objective is to engage the interest of a wide range of stakeholders. We hope that stakeholders will:

- provide input on priority topics for review, and the content and format of information that is needed and useful from their different perspectives;
- contribute technical expertise;
- be involved in developing informational messages targeted to specific audiences based on the evidence developed and conclusions/ recommendations of the Working Group; and
- provide feedback on the value of the information developed.

Other Project Activities

- Small pilot data collection studies to characterize utilization rates, identify implementation issues and assess performance in practice.
- A comprehensive evaluation of the project, including the process, the products, and the value to stakeholders.
- Development of mechanisms to sustain an ongoing systematic process for evaluation of genomic applications.

Updates on the EGAPP Project

Short updates will be sent out periodically and information will be posted on the following web site: http://www.cdc.gov/genomics/gTesting.htm.

You may unsubscribe from the mailing list at any time by emailing *EGAPP@cdc.gov*.